

### **REMARKS/ARGUMENTS**

Initially, Applicants would like to express appreciation to the Examiner for the detailed Official Action provided.

Upon entry of the above amendments, claim 1 will have been amended, and claims 15 and 21 will have been canceled without prejudice or disclaimer to the subject matter contained therein. Claims 1, 13, and 17-19 are currently pending. Applicants respectfully request reconsideration of the outstanding rejections, and allowance of all the claims pending in the present application.

#### ***Rejection under 35 U.S.C. 112, fourth paragraph***

In the Official Action, the Examiner objected to claim 21 as being in improper independent form for failing to further limit the subject matter of a previous claim.

Without acquiescing to the propriety of the Examiner's rejection, Applicants submit that claim 21 has been cancelled. Accordingly, the aforementioned rejection is believed to be moot and should be withdrawn.

#### ***Listing of the Rejections under 35 U.S.C. 102 and 103***

In the Official Action, the Examiner rejected claims 1, 13, 15, 17 and 21 under 35 U.S.C. 103(a) as being unpatentable over JP 44-5526 in view of FUKASAWA et al. (EP 0306613);

the Examiner rejected claims 1, 13, 15, 17 and 21 under 35 U.S.C. 103(a) as being unpatentable JP 63-56044 in view of FUKASAWA;

the Examiner rejected claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over JP 44-5526 and FUKASAWA, in view of KANNO et al. (U.S. Patent No. 4,201,673); and

the Examiner rejected claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over JP 63-56044 and FUKASAWA, in view of KANNO.

Without acquiescing to the propriety of the Examiner's rejections, Applicants submit that claim 1 has been amended solely in order to expedite prosecution of the presently claimed invention.

In this regard, Applicants submit that none of the applied prior art, alone or in any properly reasoned combination, discloses at least the combination of features recited in independent claim 1.

### ***Features of Claim 1***

In particular, amended claim 1 recites a hollow fiber membrane type fluid treatment device including, inter alia, the end tapered portion increasing in diameter toward an end face of the housing body portion, and the hollow fiber membranes of the hollow fiber membrane bundle are arranged so that a distance between individual hollow fiber membranes is gradually increased toward the end of the housing body portion as the hollow fiber membranes extend along a taper of the end tapered portion, thereby increasing the diameter of the hollow fiber membrane bundle.

### ***Discussion of JP 44-5526***

Applicants submit that the presently claimed invention is very different structurally from the device in JP '526.

In particular, Applicants submit that JP '526 apparently discloses that the hollow fiber membranes being bundled together within flexible sleeves and maintained in close contact. Thus, in JP '526 the sleeves are disposed near the end portion so that the distance between the sleeves increase. In other words, Applicants submit that JP '526 does not disclose the distance between individual hollow fiber membranes increasing, but rather (at best) the distances between bundled membranes increasing.

Accordingly, because the number of bundles are much less than the number of hollow fiber membranes in JP '526, Applicants submit that the tapered portion in JP '526 will not provide the same advantageous total effect of the presently claimed invention. In other words, Applicants submit that the presently claimed invention allows a distance between individual hollow fiber membranes (within a single bundle) to gradually increase toward the end face.

More simply put, Applicants submit that within a single sleeve (or bundle) the hollow fiber membranes in JP '526 are maintained in close contact. Therefore, Applicants submit that JP '526, alone or in any properly reasoned combination, does not disclose the hollow fiber membranes of the (single) hollow fiber membrane bundle being arranged so that a distance between individual hollow fiber membranes is gradually increased toward the end of the housing body portion as the hollow fiber membranes extend along a taper of the end tapered portion, thereby increasing the diameter of the hollow fiber membrane bundle, as generally recited in amended claim 1.

Furthermore, Applicants submit that there is nothing in KANNO, and FUKASAWA which can reasonably be considered to supply the above discussed deficiency in JP '526.

In particular, Applicants submit that FUKASAWA apparently merely discloses the housing 15 narrowing from both ends to *constrict* the outer periphery of the hollow fiber

membrane bundle at a central portion thereof in the axial direction. That is, Applicants submit that the fiber membranes in FUKUSAWA apparently come into contact along their entirely length and are merely constricted in the central portion; however, FUKUSAWA does not disclose the distance between the individual membranes themselves increasing. See page 5, lines 22-29 in FUKASAWA.

***Discussion of JP 63-56044***

Furthermore, Applicants submit that JP '044 apparently discloses a similar arrangement to FUKUSAWA in which the fiber bundle is merely constricted in a central portion of the housing. Additionally, Applicants note that there is a gap between the hollow fiber bundle and taper portion of JP '044.

Therefore, Applicants submit that JP '044, alone or in any properly reasoned combination, does not disclose the hollow fiber membranes of the (single) hollow fiber membrane bundle being arranged so that a distance between individual hollow fiber membranes is gradually increased toward the end of the housing body portion as the hollow fiber membranes extend along a taper of the end tapered portion, thereby increasing the diameter of the hollow fiber membrane bundle, as generally recited in amended claim 1.

***Features of Claim 1***

Further, amended claim 1 generally sets forth a hollow fiber membrane type fluid treatment device including, inter alia, the treatment liquid inlet and treatment liquid outlet being provided at a circumference of the hollow fiber membrane bundle such that a treatment liquid flows outside of the hollow fiber membranes, the hollow fiber membrane bundle configured to

allow waste in the blood to be removed through dialysis utilizing one of a diffusion phenomenon resulting from a concentration gradient and filtration resulting from a pressure gradient, wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than  $0^\circ$  and smaller than an angle defined by  $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$  (where, d1 is the diameter of the hollow fiber membrane bundle at an end face of the resin layer, d4 is an inner diameter of the body straight portion or minimum diameter portion of the housing body portion, and L4 is the length (one side) of the end tapered portion which increases in diameter toward the end face of the housing body portion), and wherein a ratio of the length of the body straight portion to the total length of the end tapered portion is 0.7 to 20, and a ratio of the inner diameter of the end tapered portion at the end face of the housing body portion to the inner diameter of the body straight portion is more than 1 and not more than 3.

### ***Discussion of the Applied Prior Art***

In setting forth the rejections, the Examiner acknowledges that the applied prior art does not disclose an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion being greater than  $0^\circ$  and smaller than an angle defined by  $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$ .

In this regard, Applicants submit that the presently claimed angle is critical in allowing the hollow fiber membranes of the (single) hollow fiber membrane bundle, arranged so that a distance between individual hollow fiber membranes, to gradually increase toward the end of the housing body portion as the hollow fiber membranes extend along a taper of the end tapered portion, thereby increasing the diameter of the hollow fiber membrane bundle.

Applicants submit that the unexpected results and critically of the end tapered portion of the presently claimed invention is supported by the present Disclosure.

See, e.g., the first paragraph in page 18 of the original disclosure which explains that “when the dialysate as the treatment liquid flows into the housing through the treatment liquid connection port 12, since the hollow fiber membrane bundle 20 in which several thousand hollow fiber membranes are bundled is uniformly increased in diameter along the tapered portion 15, a space is formed between the hollow fiber membranes... Therefore, since the surface area of the hollow fiber membrane coming in contact with the dialysate is substantially increased, the removal performance of blood wastes through the hollow fiber membrane bundle 20 is thought to be improved significantly.”

In this regard, Applicants submits that there is nothing in the applied prior art that can reasonably be considered to contemplate or suggest a relationship between selecting an upper limit of the angle (i.e.,  $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$ ) based upon the diameter of the hollow fiber membrane bundle, an inner diameter of the straight body portion, and the length (one side) of the end tapered portion.

As a result of the aforementioned features, Applicants submit that the substance removal performance is significantly increased, and the variation in the substance removal performance is little, and occurrence of leakage due to breakage of the hollow fiber membrane is significantly reduced depending on the diameter-expanding portion. (See paragraph on page 33 of the present Disclosure). Also, Applicants submit that the applied prior art does not disclose or contemplate, e.g., that an undesirable short-path may result from a particular taper or a tapered portion.

Thus, Applicants submit that the applied prior art, alone or in any properly reasoned combination, fails to disclose at least the presently claimed angle formed by a centerline of the

inner surface of the housing body portion and an inner surface of the end tapered portion being greater than  $0^\circ$  and smaller than an angle defined by  $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$  (where, d1 is the diameter of the hollow fiber membrane bundle at an end face of the resin layer, d4 is an inner diameter of the body straight portion or minimum diameter portion of the housing body portion, and L4 is the length (one side) of the end tapered portion which increases in diameter toward the end face of the housing body portion), and wherein a ratio of the length of the body straight portion to the total length of the end tapered portion is 0.7 to 20, and a ratio of the inner diameter of the end tapered portion at the end face of the housing body portion to the inner diameter of the body straight portion is more than 1 and not more than 3, as generally recited in claim 1.

Further, Applicants respectfully request that the Examiner consider the attached Declaration and accompanying data. The attached Declaration shows that even the lowest performing example (Example 8), having features corresponding to those of the present invention, demonstrated superior performance in comparison to the highest performing comparative example (Comparative Example 3), which is illustrative of the conventional art.

Accordingly, Applicants submit that the Declaration and accompanying data demonstrate the unexpected results, advantages and superior functioning associated with features of the present disclosure, and therefore, respectfully request allowance of the present application.

Additionally, Applicants also expressly incorporate all other arguments made in Applicants' previous Responses.

### ***Generally***

Accordingly, Applicants submit that the rejections of claims 1, 13, 15, 17-19 and 21 under 35 U.S.C. §103 are improper and should be withdrawn.

In view of the arguments herein, Applicants submit that independent claim 1 is in condition for allowance. With regard to dependent claims 13 and 17-19, Applicants assert that these claims are allowable on their own merit, as well as because they depend from independent claim 1 which Applicants have shown to be allowable.

Thus, it is respectfully submitted that all of the claims in the present application are clearly patentable over the references cited by the Examiner, either alone or in combination, and an indication to such effect is respectfully requested, in due course.



**SUMMARY**

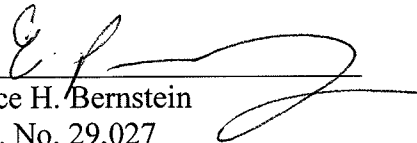
Applicants submit that the present application is in condition for allowance, and respectfully requests an indication to that effect. Applicants have argued the allowability of the claims and pointed out deficiencies of the applied references. Accordingly, reconsideration of the outstanding Official Action and allowance of the present application and all the claims therein are respectfully requested and is now believed to be appropriate.

Applicants submit that this amendment is being made to advance prosecution of the application to allowance and should not be considered as surrendering equivalents of the territory between the claims prior to the present amendment and the amended claims. Further, no acquiescence as to the propriety of the Examiner's rejection is made by the present amendment. All other amendments to the claims which have been made in this amendment, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

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Should the Examiner have any questions or comments regarding the present response or this application, the Examiner is respectfully invited to contact the undersigned at the below listed number.

Respectfully submitted,  
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